UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

30/JAN/2014

MEMORANDUM

Subject:	Name of Pesticide Product:	UP-CYDE PRO 2.0 EC Termiticide/Insecticide
	EPA Reg. No. /File Symbol:	70506-19
	DP Barcode:	D416182
	Decision No:	484176
	Action Code:	R340
	PC Code:	109702 (cypermethrin)
From:	Eugenia McAndrew, Biologist Technical Review Branch Registration Division (7505P)	E McAndrew 1/31/14
To:	Linda DeLuise, RM Team 10 Insecticide Branch Registration Division (7505P)	
Applicant:	United Phosphorus, Inc. 630 Freedom Business Center King of Prussia, PA 19406	

TOXICOLOGY

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Cypermethrin	24.8
Other Ingredient(s):	75.2
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests: "Please review data and data matrix to remove RUP and go from warning to caution. New Acute Oral study."

BACKGROUND: United Phosphorus, Inc. is seeking to amend the registration for UP-CYDE PRO 2.0 EC Termiticide/Insecticide, EPA Reg. No. 70506-19. The registrant is requesting that the signal word be changed from WARNING to CAUTION and that the precautionary statements be revised to denote a Category III for acute oral toxicity. The registrant has submitted a new acute oral toxicity study (MRID 49240501) to support these changes.

In 2010, six acute toxicity studies (MRIDs 480547-01 to -06) were submitted to support the reregistration of 70506-19. The toxicity categories assigned were all III or IV except for the acute oral toxicity study which was assigned to category II based on an acute oral LD_{50} = 166. 32 mg/kg. The review indicated that 70506-19 met the criteria for a Restricted Use Product and Child Resistant Packaging (Vinjamuri; D372078; EPA Reg. No. 70506-19; 21/MAY/2010).

The registrant explains the reason for this new submission in a letter dated October 10, 2013:

> The RUP statement (and child resistant packaging) was imposed on this product because the Agency review indicated that the LD_{50} was < 1500 mg/kg (1.5 g/kg) and the label had the residential uses. However, according to 40 CFR 152.70 the criteria for the RUP in addition to the residential use is that the pesticide have an acute oral LD_{50} of 1.5 g/kg or less *when diluted* (emphasis added). It is our intent by way of this submission to provide the Agency with the information required to remove the RUP statement based on new oral toxicity data, and change the signal word from WARNING to CAUTION based on the overall toxicity profile.

The new acute oral toxicity study submitted (MRID 49240501) is conducted on a 1% dilution of UP-CYDE PRO 2.0 EC Termiticide/Insecticide, EPA Reg. No. 70506-19. The label submitted for 70506-19 shows that the product is intended to be used at concentrations of 0.25% to 1.0%.

DISCUSSION/RECOMMENDATIONS:

1. The acute oral toxicity study (MRID 49240501) is acceptable in Toxicity Category III with an acute oral LD_{50} > 1550 mg/kg. According to AOT425StatPgm (Version 1.0), which is the statistical program used to determine dosing and calculate the LD_{50} for the up and down procedure, at least one more animal should have been tested at the limit dose. However, in this case, given the results of the previous acute oral toxicity study, we can accept this study.

acute oral toxicity	III (LD_{50} > 1550 mg/kg as a 1% dilution)	acceptable	MRID 49240501

2. The registrant is correct that 40 CFR 152.70 does state that in order to meet the criteria for RUP, the pesticide must have residential uses and an acute oral LD_{50} of 1.5 g/kg or less as diluted for use. The new oral study submitted demonstrates that the product has an acute oral LD_{50} > 1550 mg/kg as diluted for use. Therefore, the product does *not* meet the criteria for RUP.

3. The product still meets the criteria for Child Resistant Packaging because 40 CFR 157.22 refers to the product itself and not the dilution.

4. The acute toxicity category for the oral route of exposure remains category II based on the product as formulated. Therefore, the signal word remains WARNING.

5. The acute toxicity profile for UP-CYDE PRO 2.0 EC Termiticide/Insecticide, EPA Reg. No. 70506-19, cited from the 2010 Pesticide Re-evaluation Division memo (Vinjamuri; D372078; EPA Reg. No. 70506-19; 21/MAY/2010) remains unchanged as follows:

acute oral toxicity	II (LD_{50} > 166.32mg/kg)	cited	MRID 48054701
acute dermal toxicity	III (LD_{50} > 2000 mg/kg	cited	MRID 48054702
acute inhalation toxicity	IV (LC_{50} > 2.118 mg/L)	cited	MRID 48054703
primary eye irritation	III	cited	MRID 48054704
primary skin irritation	IV	cited	MRID 48054705
dermal sensitization	sensitizer	cited	MRID 48054706

GLP: The acute oral toxicity study (MRID 49240501) was conducted in accordance with GLP.

DEFICIENCIES: None

REVISED LABEL STATEMENTS:

PRODUCT ID #: 070506-00019

PRODUCT NAME: UP-CYDE PRO 2.0 EC Termiticide/Insecticide

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

SPANISH SIGNAL WORD: AVISO
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

May be fatal if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]*

*[Protective eyewear may be specified, if appropriate.]

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

User Safety Recommendations:

- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.
-Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
-Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Product Reg. No.: 70506-19
Product Name: UP-CYDE PRO 2.0 EC Termiticide/Insecticide

The following table is the Acute Toxicity Data Evaluation Record (DER) for the acute oral toxicity study submitted for EPA Reg. No. 70506-19:

1. DP BARCODE: D416182				
2. PC CODE: 109702				
3. CURRENT DATE: January 30, 2014				
4. TEST MATERIAL: Up-Cyde Pro 2.0 EC Termiticide/Insecticide (Batch # 508-55A; 24.4% cypermethrin; yellow liquid; pH 4.8% (1% emulsion in water). The sample was administered as a 1% AI w/v of active ingredient dosing solution with distilled water.)				
Study/Species/Lab Study # /Date	**MRID**	**Results**	**Tox Cat**	**Core Grade**
Acute oral toxicity/ rat PSL/Study # 36936/ September 25, 2013 OCSPP 870.2400; OECD 425	49240501	D_{50} > 1550 mg/kg 3 animals tested in limit dose test at 1550 mg/kg Test sample was administered as 1% AI w/v dilution. All animals survived and gained weight. No clinical signs or abnormalities at necropsy were observed.	III	A

Core Grade Key: A =Acceptable, S = Supplementary, W = Waived, U = Unacceptable, D = Data Gap